



OCT 22 2004

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Ms. Kathy Woodward
Great Earth Companies
1101 S. Millikin Ave., Suite A
Ontario, CA 91761

Dear Ms. Woodward:

The Food and Drug Administration (FDA) has reviewed your product labeling, including your web site at the Internet address <http://www.cytodyne.com> and has concluded that claims in your labeling cause your product "Xenadrine CarboCurb" to be misbranded under the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and FDA's regulations through links on FDA's Internet home page: <http://www.fda.gov>.

Under section 403(r)(6) of the Act, dietary supplement labeling may include claims about the supplement's effect on the structure or function of the human body (structure/function claims), provided that certain requirements are met. 21 U.S.C. § 343(r)(6)(A). One of these requirements is that the manufacturer of a dietary supplement bearing a "structure/function" claim must have substantiation that the claim is truthful and not misleading. [21 U.S.C. § 343(r)(6)(B).]

The labeling of Xenadrine CarboCurb bears structure/function claims, including the following:

- "Helps Reduce Simple & Complex Carbohydrate Absorption."
- "Xenedrine CarboCurb ... helps reduce carbohydrate absorption in the foods you eat, and may also help reduce the amount of glucose derived from carbs and protein."
- "[H]elp reduce the amount of potential carbohydrates absorbed by your body...also help limit the amount of carbs that turns into glucose, and help burn body fat."
- "This product is a blend of...Northern white kidney bean extract(KBE).... The weight loss properties of KGE [sic] were demonstrated in a 12-week randomized placebo-controlled, double blind study. Body composition measurements showed that at least 85% of the weight reduction in the KBE group was fat loss."
- "Xenedrine also includes green tea extract, which has been demonstrated in a randomized, placebo-controlled study to increase weight loss and burn calories."

- With regard to the green coffee bean extract in Xenedrine CarboCurb ... human research has shown that chlorogenic acid in coffee has the ability to reduce the amount of carbohydrates absorbed."

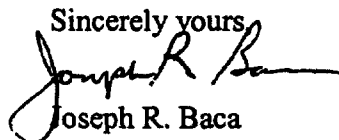
We have reviewed these claims and have concluded that they are not supported by competent and reliable scientific evidence. Because these claims lack substantiation, they are false or misleading, and cause your product to be misbranded within the meaning of sections 403(a)(1) and 403(r)(6)(B) of the Act. [21 U.S.C. § 343(a)(1), (r)(6)(B).] It is a violation of section 301(a) of the Act to introduce or deliver for introduction into interstate commerce any food, including a dietary supplement, that is misbranded. [21 U.S.C. § 331(a).] It is a violation of section 301(k) of the Act to commit any act with respect to a food if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being misbranded. [21 U.S.C. § 331(k).]

This letter is not an all-inclusive review of your web site and the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

You should take prompt action to correct any violations, including the violations identified in this letter. Failure to do so may result in enforcement action, including seizure or injunction, without further notice.

If you have scientific evidence which you believe substantiates that your claims for Xenadrine Carbo-Curb are truthful and not misleading, please provide it to us within fifteen (15) working days of receipt of this letter. Alternatively, please advise this office, in writing and within fifteen working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to ensure that similar violations do not occur in the future. If corrective action cannot be completed with fifteen working days, state the reason for the delay and the time within which the corrections will be made.

Your reply should be sent to the attention of Compliance Officer Quyen Tien at the above address.

Sincerely yours,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety and Applied Nutrition